



901 E. 233rd Street Carson, California 90745-6204 310/835-8400 Fax 310/835-6615

December 15, 1998

Office of Special Nutritional (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" Street SW 2 3 4 6 '99 JAN -5 P2:14
Washington, DC 20204

Section 403(r)(6) Notification

Dear Sir or Madam:

In accordance with the requirement of section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, Leiner Health Products notifies the FDA that it has begun using the following phrase and statement:

Helps maintain healthy heart function & regulate cholesterol

Clinical research has shown that consumption of garlic may help promote healthy heart function and regulate cholesterol levels. May help the Garlic to fully absorb in the intestine where the beneficial ingredients in garlic can best help regulate heart health. Maintains Healthy Heart Function Helps Regulate Cholesterol Levels

on the following product:

YourLife® Advanced Strength Garlic

Very truly yours,

Leiner Health Products

Gale Bensussen, President

cc: Michael Bradley, Director of Regulatory Affairs
William Cochran, Manager of Regulatory Affairs